

Attorney Docket No.: **TI-0013**  
Inventor: **Taylor et al.**  
Serial No.: **09/802,466**  
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#### **REMARKS**

Claims 1, 2, 4, 6-11, 21, and 26-28 are pending in the instant application. Claims 1, 2, 4, 6-11, 21, and 26-28 have been rejected. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Rejection of Claims Under 35 U.S.C. §103**

##### *A. Gjerde et al. as Primary Reference*

Claims 1, 2, 4, 6-11, 21, and 26-28 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Gjerde et al. (U.S. Patent Application No. 2003/0165941) in view of Bloch (U.S. Patent No. 5,866,429). It is suggested that Gjerde et al. teach separation of polynucleotides by Matched Ion Polynucleotide Chromatography (MIPC) in accordance with the claimed methods; however, this reference does not teach that the column has an inner diameter of greater than 5.0 mm. The Examiner suggests that Bloch is drawn to methods of separating nucleic acids and therefore, is drawn to solving similar problems in the art as Gjerde et al. It is suggested the Bloch teaches that the column is the most important component, wherein the column can be no greater than 10 mm, *i.e.*, naturally encompassing diameters greater than 5 mm. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of filing to include the internal diameter sizes taught by Bloch with the method of separation of RNA molecules taught by Gjerde et al. because Gjerde et al. teach that it is within the ordinary skill of the art to separate RNA using non-polar separation medium in

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which a mobile phase is passed through to elute RNA and because Bloch teaches that it is within ordinary skill in the art to use columns with internal diameters of greater than 5 mm. It is suggested that one would have been motivated to do so in order to receive the expected benefit of preferred components of RNA separation. Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's conclusion regarding the motivation to modify the teachings of Gjerde et al. to employ columns having an internal diameter of greater than about 5.0 mm as taught by Bloch. The teachings of Bloch are drawn to separating nucleic acids based upon charge whereas the nucleic acid separations of Gjerde et al. are based upon polar properties of the nucleic acids. These are distinct separation methodologies with distinct products. In any event, Gjerde et al. is not a valid prior art reference. At the time of filing of the present application, the inventors of the instant application and Patent Application No. 2003/0165941 had a common obligation to assign to Transgenomics, Inc. (see the face of Patent Application No. 2003/016594). Accordingly, because there would be little motivation to combine the cited references and Gjerde et al. is not a valid prior art reference, the instant invention is not obvious in view of Gjerde et al. and Bloch. It is therefore respectfully requested that this rejection be withdrawn.

*B. Gjerde et al. as Primary Reference*

Claims 7-10, 26 and 28 also remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner (U.S. Patent No. 6,453,244) in view of Bloch. It is suggested that Oefner teaches separation of polynucleotides MIPC in accordance with the claimed

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methods; however, this reference does not teach that the column has an inner diameter of greater than 5.0 mm. The Examiner suggests that Bloch teaches that the column is the most important component, wherein the column can be no greater than 10 mm, i.e., naturally encompassing diameters greater than 5 mm. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time of filing to include the internal diameter sizes taught by Bloch with the method of separation of RNA molecules taught by Oefner because Oefner teaches that it is within the ordinary skill of the art to separate RNA using non-polar separation medium in which a mobile phase is passed through to elute RNA and because Bloch teaches that it is within ordinary skill in the art to use columns with internal diameters of greater than 5 mm. It is suggested that one would have been motivated to do so in order to receive the expected benefit of preferred components of RNA separation.

Claims 1, 2, 4, 6 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner, in view of Bloch, further in view of Petro et al. (U.S. Patent No. 6,260,407).

Claims 11 and 27 also remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oefner, in view of Bloch, further in view of Petro et al., further in view of Sheridan and Sheridan ((1989) *Scientist* 3(4)23).

Applicants respectfully traverse these rejections.

MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an

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aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.).

In this regard, Oefner teaches reversed-phase columns with an inner diameter of 4.6 mm (see Example 1 and Example 2). Oefner does not teach or suggest variability in the inner diameter of the column. Similarly, Bloch exemplifies an anion exchange column with an inner diameter of 4.6 mm (see Example 1) and suggests columns that preferably will not exceed 5 mm (see column 17, lines 21-23). Accordingly, there would be little motivation for one of skill in the art to look to the anion exchange columns of Bloch and apply columns of inner diameters of greater than 5 mm to the reversed-phase columns of Oefner because there is simply no teaching or suggestion to do so. Moreover, neither of these references teach nor suggest that column diameter is a result-effective variable, i.e., a variable which achieves a recognized result. MPEP 2144.05. Therefore, there would be no motivation to use a column inner diameter of greater than 5 mm because the cited references fail to teach or suggest that column inner diameter is a result effective variable that achieves improved separation of RNA. Because Petro and Sheridan & Sheridan fail to

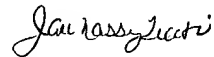
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compensate for the deficiencies in the primary and secondary reference, the combined references fail to make the instant invention obvious. It is therefore respectfully requested that these rejections be withdrawn.

## **II. Conclusion**

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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